REMARKS/ARGUMENTS

Claim 17, 18, 30-41 and 44 were pending and were examined. The claims have been amended as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

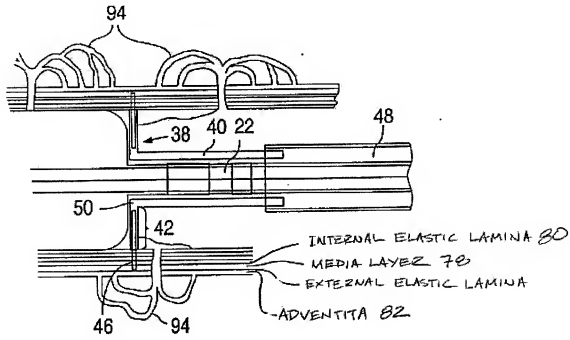
Applicants thank Examiner Witczak for the courteous and helpful interview on June 25, 2008. At that interview, Applicants described the advantages of confirming that the delivery aperture of a needle be advanced beyond the external elastic lamina of a blood vessel prior to injecting substances into the tissue surrounding the blood vessel. Applicants further described, and the Examiner recognized, that the Ray '712 publication teaches injecting substances into the tunica media layer within the blood vessel wall, not beyond the external elastic lamina into the adventitia beyond the blood vessel wall. The more detailed reasoning is set forth below.

The presently pending claims include a single independent claim 17, as well as a number of claims dependent thereon. Independent claim 17 recites two limitations of particular interest. First, the method requires that a agent delivery needle be positioned outwardly from a blood vessel lumen "into tissue beyond an external elastic lamina (EEL) of the blood vessel." and further that the position of the needle beyond the EEL be confirmed "before injecting the pharmaceutical agent."

The Examiner has relied on the Ray '712 publication as teaching the positioning of an injecting needle beyond the EEL of a blood vessel and further on Greff '714 to teach use of a contrast agent to confirm the position of a needle. Applicants disagree with the characterization of Ray and further argue that one skilled in the art looked to Greff for any other teaching for confirming the position of the needle without the recognition of the desirability of positioning the needle beyond the EEL.

The Ray patent nowhere teaches positioning a drug injection lumen beyond the external elastic lamina. In fact, in contrast, Ray teaches specifically that the "needle 46 should be calibrated so that it is capable of penetrating into the tunica media 78 layer to inhibit proliferation and migration of the SMC and the development of ECM." See paragraph [0038].

This can be seen from a portion of Fig. 6, reproduced below, the needle never penetrates into the adventitia 82 and, although not illustrated, it is noted that the external elastic lamina is located between the tunica media layer 78 and the adventitia 82. For this reason alone, the present rejection of claim 17 must fail.



Even if the prior art were to teach that it is possible to extend the needle into the adventitia or other regions of the perivascular space, however, the teachings of Greff '714 would be irrelevant until it is recognized that the needle must be properly positioned before delivering the drug. No where in Ray, Greff, or any other art present of record are known to the Applicants, however, is there any such teaching.

In an effort to even further distinguish the teachings of Ray '712, however, Applicants have amended claim 17 to clarify that the needle is advanced from the blood vessel lumen "through the blood vessel wall and past ...[the] ... external elastic lamina" and that the pharmaceutical agent is injected through the needle "after it has been confirmed that the aperture of the needle is positioned beyond the external elastic lamina."

For those reasons, Applicants believe that independent claim 17, as well as all claims dependent thereon, are in condition for allowance.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

James M. Heslin
Reg. No. 29,541

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 415-576-0300
JMH:jke/vp
61405257 v1